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Liver-FibroSTARD Checklist and Glossary: Tools for Standardized Design and Reporting of Diagnostic Accuracy Studies of Liver Fibrosis Tests

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Editorial

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Chronic liver diseases are highly prevalent and require an accurate evaluation of liver fibrosis to determine patient management. Many efforts have been made over this last decade to develop accurate non-invasive tools for liver fibrosis evaluation as alternative methods to liver biopsy. These non-invasive methods of liver fibrosis assessment including blood markers and liver stiffness measurement by elastography are increasingly well validated and contribute to safer and more practical clinical care for patients [1, 2]. These efforts have led to a dramatic increase in the number of diagnostic accuracy studies of liver fibrosis tests and to a proliferation of reports whose quality is very heterogeneous.

The validation of the diagnostic test is a critical issue for their widespread use in clinical practice [3]. The results of diagnostic accuracy studies are the basis to inform how to interpret test results and to consider the likelihood that errors occur in clinical decision. Guidelines aim to help for reporting the researches more completely to ensure that the papers are more useful and are not misleading [4]. The Standards for Reporting of Diagnostic Accuracy Studies (STARD), simultaneously published in 2003 in 13 biomedical journals, including *Clinical Chemistry and Laboratory Medicine* [5] were developed aiming to "improve the accuracy and completeness of reporting of studies of diagnostic accuracy, to allow readers to assess the potential for bias in the study (internal validity) and to evaluate its generalizability (external validity)". The STARD checklist, comprising 25 items summarizing the important information that has to be present in scientific reports, has been included in the instructions to authors of more than 200 scientific journals. Over the years, the reporting of many individual STARD items improved however, the STARD authors agreed that these statements should be updated [6] and the original checklist was supplemented with guidance pertinent to studies of specific disorders in human [7–9], veterinary medicine [10] or epidemiology [11].

For the diagnostic accuracy studies of non-invasive liver fibrosis tests, the STARD criteria represent an excellent base to start off. However, these studies have particular features that are not taken into account by the current STARD statements. While fibrosis staging is of high clinical significance in patients with chronic liver diseases, the difficulties due not only to the absence of an absolute gold standard (liver biopsy examination is a limited "gold" standard [12]), but also to the spectrum bias [13], and to the specificities for ordinal references such as pathological staging [14] made essential to develop specific validated standards of study design and reporting.

A group of eight experts of different specialties (hepatology, biology, radiology, pathology, and biostatistics) chosen by the board of the French Association for the Study of the Liver [Association Française pour l'Étude du Foie (AFEF)] evaluated STARD statements adequacy in 10 diagnostic studies about non-invasive liver fibrosis tests, and considered than more than a half of the 25 STARD items were only partially adequate for this purpose [15]. Therefore, they attempted to establish a consensus for quality standards by adapting the STARD criteria to the requirements of liver fibrosis testing and then developed an extended version developed specifically for those studies. The process resulted in introducing two new items and 42 sub-items within the 25 STARD items [16]. A comprehensive glossary including explanations and examples for each item/sub-item was also drafted and approved by the panel of experts [17].

The Liver-FibroSTARD checklist and glossary were independently submitted to seven international experts in order to test and validate the new standard statements.

The independent evaluation showed at least very good inter-expert agreement for two thirds of the items/sub-items [15]. After this second external evaluation, material was finally improved. The new Liver-FibroSTARD checklist [16] and glossary [17] are freely available at the URLs mentioned in these references.

An accelerated development of improved markers has been recommended in order to integrate non-invasive tests of liver fibrosis as endpoints into future clinical trial design of antifibrotic drug [18]. High-quality studies are required for validation of cut-offs to stage fibrosis according to the etiologies of chronic liver diseases [19]. As a supplement of the STARD statements, the Liver-FibroSTARD checklist and its glossary are new tools specifically designed for the evaluation of diagnostic studies about non-invasive liver fibrosis tests. Liver-FibroSTARD statements should allow improving design and reporting in this field and could be the beginning of an iterative process by which reporting standards will be continuously improved.

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